NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 September 2023 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Miss R Anderson	
Dr V Chieng	Mrs S Howlett	
Dr D Culligan	Mrs G McKerron	
Ms A Davie		
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Dr M Metcalfe (Vice-Chair) (to item 8.6)		
Mrs E Milne		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

ITEM	SUBJECT	ACTION
	WELCOME	
	The Chair welcomed members, opened the meeting, and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 15 AUGUST 2023**	
	The Group accepted the draft note of the meeting subject to minor typographical changes.	
	The corrected final approved minute will be in the public domain within 21 days of final approval.	**FD**
3.	**PRESENTATION/DISCUSSION**	
	None.	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	The action log was noted.	
	No additional items were identified for discussion at the meeting.	
	4.2. LUFORBEC®	
	The Chair reported that the Marketing Authorisation Holder (MAH) has confirmed that from the 1st November the List price of Luforbec® pressurised metered dose inhaler (pMDI) will change from £20.52 per pack to £13.98 per pack.	
	Item closed.	**FTEAM**

ITEM	SUBJECT	ACTION

5. FORMULARY GROUP DECISIONS AUGUST 2023 - PUBLISHED 28/08/2023

The Chair confirmed that due to issues with the link to the decisions document, an updated link would be sent, with an extension to the end of the week for members to ratify the decisions of the August 2023 meeting. **ALL**

The Formulary Team will issue an updated link after the meeting. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. METRELEPTIN (MYALEPTA®)

Mrs Standen reported that from 07 September 2023 metreleptin can be prescribed in the Scottish Government ultra-orphan medicines pathway.
The formulary entry will be updated to highlight that if local need identified, 'treatment is available through the National Services Scotland Ultra-orphan medicines Risk Share Scheme'. **FTEAM**

6.2. BUPRENORPHINE HIGHER STRENGTH PATCHES

There were no declarations of interest recorded in relation to these products.

Mrs Standen reported that:
- buprenorphine patches are already included on the formulary
- the Medicines Management Team has requested that Bupeaze® is noted on the formulary as the preferred brand of buprenorphine higher strength patches
- the Specialist Pharmacy Service (SPS) recommends that buprenorphine patches are prescribed by brand to reduce the risk of confusion and errors in dispensing and administration, as different brands of the higher strength patches are applied at different frequencies
- buprenorphine is a Schedule 3 Controlled Drug, so is subject to prescription and safe custody requirements
- Bupeaze® patches should be replaced every 4 days at the latest, and is currently the most cost-effective high strength patch
- for convenience of use, the patch can be changed twice a week at regular intervals, e.g., Monday and Thursday

Members supported the request to update the formulary to note Bupeaze® as the preferred brand of high strength buprenorphine patch, with the alternatives noted as 'not preferred/non-formulary'. **FTEAM**

6.3. ACALABRUTINIB (CALQUENCE®)

Mr Paterson declared a personal, non-specific interest in relation to AstraZeneca UK Limited.

Mrs Standen reported that:
- acalabrutinib is included on the formulary as the capsule formulation
- the tablet formulation is considered outwith remit for the SMC
- the MAH confirmed that:
  - stocks of the tablets will be available in the UK early August 2023
  - in the UK, the capsule formulation is expected to be discontinued approximately 6 months after acalabrutinib tablets are marketed
  - the tablets have demonstrated the same efficacy and safety as the capsules and patients can be switched without any treatment interruption
- the PAS paperwork has been updated to include the new formulation and the NHS list price and PAS discount is the same for both formulations
- stocks of capsules are being run down ready for the switch to tablets

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The Group accepted the restricted local need for acalabrutinib film-coated tablets in line with the SMC advice for the capsule formulation (including restrictions) without the need for a submission.

Acalabrutinib 100mg film-coated tablets (Calquence®) is routinely available in line with national guidance (SMC 2346, SMC 2347, SMC 2348).
Indication under review: as monotherapy for the treatment of adults with:
- **previously untreated chronic lymphocytic leukaemia (CLL) who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable**
- **with relapsed/refractory CLL who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable**
- **previously untreated CLL without a del(17p) or TP53 mutation and who are ineligible for fludarabine, cyclophosphamide and rituximab (FCR) therapy**

This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

The formulary entry for acalabrutinib 100mg hard capsules will be changed, noting that the capsules are being withdrawn and replaced by film-coated tablets. **FTEAM**

7. OTHER BUSINESS

7.1. SCOTTISH GOVERNMENT CONSULTATION ON THE DRAFT "QUALITY PRESCRIBING FOR RESPIRATORY – A GUIDE FOR IMPROVEMENT 2024-2027".

The Scottish Government has launched a consultation on the draft "Quality prescribing for respiratory – a guide for improvement 2024-2027". The consultation is open for responses until 31 October 2023.
The guide is promoting Realistic Medicine using the holistic Polypharmacy 7-Steps approach.
There is a section on the environmental impact of inhalers and it is recommending that local formularies are updated to highlight and promote inhalers which have lower carbon dioxide emissions.
The Respiratory Managed Clinical Network (MCN) is looking at the guide and will be leading on the recommendations.

8. NEW PRODUCT REQUESTS

8.1. FG1 455/22 - RIVAROXABAN (PREVENTION OF ATHEROTHROMBOTIC EVENTS IN PAD)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for rivaroxaban (in combination with aspirin) for the prevention of atherothrombotic events in adults with symptomatic peripheral artery disease (PAD) at high risk of ischaemic events, with use restricted to adults who underwent a successful revascularisation procedure (complex endovascular intervention, surgical bypass or hybrid intervention) treated for critical limb-threatening ischaemia (CLTI) or aneurysmal disease.

The Group noted that:
- in February 2019, rivaroxaban 2.5mg tablets were accepted for restricted use within NHS Scotland, co-administered with acetylsalicylic acid, for the prevention of atherothrombotic events in adults with coronary artery disease (CAD) that is stable and does not require dual antiplatelet therapy (SMC 2128)
- rivaroxaban 2.5mg is also licensed for the prevention of atherothrombotic events in adults with symptomatic PAD at high risk of ischaemic events. This indication was not

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included in SMC 2128 because the MAH requested that SMC only considered rivaroxaban when positioned for use in patients who have CAD that is stable and does not require dual antiplatelet therapy.
- at that time, the Cardiology Service decided not to proceed with a local submission
- the recommended dose of rivaroxaban is 2.5mg twice daily, and the treatment duration is determined individually for each patient based on regular evaluations considering the risk of thrombotic events versus the bleeding risk
- evidence for people with PAD comes from COMPASS and VOYAGER-PAD
- in COMPASS
  - the primary outcome was cardiovascular death, stroke or myocardial infarction, and this occurred in 4.1% (n=379), 4.9% (n=448) and 5.4% (n=496) for rivaroxaban plus aspirin, rivaroxaban and aspirin respectively
  - major bleeding events occurred in more patients in the rivaroxaban-plus-aspirin group than in the aspirin-alone group (3.1% (n=288) vs 1.9% (n=170))
  - similar results were observed in the PAD subgroup for primary outcome event; 5.1% (n=126) vs 6.9% (n=174), and for major bleeding; 3.1% (n=77) vs 1.9% (n=48) for rivaroxaban plus aspirin vs aspirin alone respectively.
- in VOYAGER-PAD
  - the primary outcome was acute limb ischemia, major amputation for vascular causes, myocardial infarction, ischemic stroke, or death from cardiovascular causes, and this occurred in 15.5% (n=508) with rivaroxaban plus aspirin group versus 17.8% (n=584) with aspirin
  - thrombolysis in myocardial infarction major bleeding occurred in 1.9% (n=62) with rivaroxaban plus aspirin and 1.35% (n=44) with aspirin
- the service has stated that treatment should be reviewed every 12 months, considering the risk for thrombotic events versus the bleeding risk and proposes that the review is carried out in primary care
- the service has defined stopping criteria:
  - in the event of full anticoagulation being indicated
  - if major bleeding events occur, as per the definition provided by the International Society on Thrombosis and Haemostasis (ISTH)
  - if there is a clinically relevant minor bleeding event as per ISTH. The risks and benefits of continuing therapy should be reviewed if a clinically relevant minor bleed occurs.
  - the revascularisation procedure which indicated initial regimen prescription is found thrombosed it is at the discretion of the Vascular physician to consider treatment discontinuation
- costs will be cumulative as rivaroxaban may be taken lifelong

Members discussed the request, noting that replies to queries are awaited.

Members agreed that treatment reduces morbidity and mortality, but at an increased risk of bleeding. As well as the questions already posed, members requested clarity on the following points:
- what monitoring is required, does it change with a patient's clinical circumstances, e.g., changes in creatinine clearance. Is it different to the monitoring in the current direct oral anticoagulant (DOAC) guidance?
- how much counselling is done at initiation of treatment, including discussion of the risks of treatment? Are leaflets given to patients to support their understanding of the treatment regimen and risk balance?

Members agreed that a protocol was needed to support prescribing (and monitoring in Primary Care).

Members deferred decision-making to a future meeting pending replies to the questions posed to the requestor. FTEAM

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8.2. SMC 2461 - ROXADUSTAT (SYMPTOMATIC ANAEMIA ASSOCIATED WITH CKD)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for roxadustat for the treatment of adults with symptomatic anaemia associated with chronic kidney disease (CKD).

The Group noted that:

- the MAH asked SMC to only consider use in patients who were non-dialysis dependent (NDD) at the time of treatment initiation
- roxadustat:
  - offers an alternative to erythropoiesis stimulating agents (ESA) in the treatment of anaemia associated with CKD
  - [in trials] was non-inferior to darbepoetin-alfa for the primary outcome, haemoglobin (Hb) response, and it was superior to placebo
  - offers patients an oral tablet, rather than an injection that requires refrigeration
  - is taken orally three times a week, not on consecutive days, with the dose individualised to achieve and maintain the target Hb levels
- patients should have adequate iron stores prior to initiating treatment
- the service plans to:
  - adapt the treatment protocol included in the papers
  - offer roxadustat to any new patients, and offer a switch to roxadustat for patients currently on ESA for renal anaemia who are not dialysis dependent
- in the trial the mean weekly roduxostat dose was 223.2mg
- the service proposes that roxadustat will be prescribed in primary care
- cost-offset is available from displacement of ESA
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of roxadustat

Members discussed the need for regular monitoring, particularly at the start of treatment, and agreed that prescribing should not be transferred to Primary Care until Hb is stable. Members noted the service plans to adapt the protocol submitted, and agreed that this will support prescribing, including clarifying the required monitoring.

The Group accepted the restricted local need for roxadustat for the treatment of adults with symptomatic anaemia associated with CKD who are NDD at the time of treatment initiation, in line with SMC 2461. Prescribing should remain with the specialist service until Hb is stable, on transfer of prescribing to Primary Care the specialist team will continue to monitor results and advise on dose changes (including dose adjustment for statins).

SMC 2461 - Roxadustat 20mg, 50mg, 70mg, 100mg, 150mg film-coated tablets (Evrenzo®) is routinely available in line with national guidance (SMC 2461).
Indication under review: treatment of adults with symptomatic anaemia associated with chronic kidney disease (CKD) who are non-dialysis dependent (NDD) at the time of treatment initiation.
Roxadustat was non-inferior to an erythropoiesis stimulating agent and superior to placebo for improving haemoglobin levels in adults with anaemia in CKD who were NDD.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover.
Treatment with roxadustat should be initiated by a physician experienced in the management of anaemia. All other causes of anaemia should be evaluated prior to initiating therapy with roxadustat, and when deciding to increase the dose. FTEAM

ITEM SUBJECT ACTION

8.3. SMC 2513 - NINTEDANIB (IDIOPATHIC PULMONARY FIBROSIS (IPF))

There were no declarations of interest recorded in relation to this product.

The Group considered the request for nintedanib for the treatment of idiopathic pulmonary fibrosis (IPF) in patients with a predicted forced vital capacity (FVC) greater than 80%.

The Group noted that:

- nintedanib, as Ofev®, is included on the formulary for the treatment of adults with IPF and a predicted FVC less than or equal to 80%
- the recommended dose is 150mg twice a day given orally
- nintedanib reduced the rate of decline in FVC by 125.3mL per year in INPULSIS-1 and by 93.7mL per year in INPULSIS-2, the results were statistically significant. The results from the TOMORROW study were consistent with a reduction in the rate of FVC decline of approximately 131mL per year with nintedanib, but statistical significance was not reached for the primary analysis.
- the results from the open-label extension studies, INPULSIS-ON and TOMORROW, suggest that the reduction in the rate of annual decline in FVC is maintained beyond 4 years
- FVC is not a direct health outcome and has been used as a surrogate marker for other direct outcomes such as mortality
- the service plans to initiate supply in hospital before transfer to homecare when patients are stable on treatment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Ofev®
- this represents a new cost to the system (new group of patients eligible for treatment)

The Group accepted the restricted local need for nintedanib, as Ofev®, for the treatment of adults with IPF in patients with a predicted FVC >80%.

SMC 2513 - Nintedanib 100mg, 150mg soft capsules (Ofev®) is routinely available in line with national guidance (SMC 2513).
Indication under review: for the treatment of adults with idiopathic pulmonary fibrosis (IPF) in patients with a predicted forced vital capacity (FVC) >80%.
Nintedanib, compared with placebo, reduces the decline in pulmonary function assessed by FVC in patients with IPF.
This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
Nintedanib (Ofev®) has previously been accepted for restricted use in adults with IPF with a predicted FVC ≤80% (SMC 1076/15); this advice remains valid.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by physicians experienced in the management of diseases for which Ofev® is approved. FTEAM

8.4. FG1SMC 2536 - DARATUMUMAB (NEWLY DIAGNOSED MULTIPLE MYELOMA)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for daratumumab, in combination with lenalidomide and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).

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The Group noted that:

- September 2023, daratumumab, used in combination with lenalidomide and dexamethasone (D-Rd) for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT) (SMC 2536), was accepted for use in NHS Scotland following a full submission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- although both the infusion and the injection are accepted for use, the subcutaneous product would be the preferred formulation, due to its lower service implications
- evidence for this indication comes from the ongoing MAIA study
- treatment was given until disease progression (median follow-up of >5 years)
- D-Rd vs. Rd showed statistically significant difference in progression-free survival (PFS) and the Kaplan–Meier estimated overall survival (OS) favoured D-Rd
- despite more than five years follow-up, the OS data is still immature because there is no OS data for D-Rd yet (median not yet reached); the median OS for Rd is 64.4 months
- the addition of D-Rd had no notable impact on health-related quality of life
- intravenous (IV) and subcutaneous (SC) formulations showed little differences in the adverse events
- the service has significant experience using daratumumab, and the safety profile of the regimen is known and manageable
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of daratumumab

Members discussed the significant cost of the first-line treatment regimen, noting the high cost despite the availability of generic lenalidomide, and although cost offset is available from displacement of use further down the pathway, when used first-line patients will remain on treatment longer.

The Group accepted the restricted local need for daratumumab, in combination with lenalidomide and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for ASCT, as outlined in SMC 2536.

SMC 2536 - Daratumumab 20mg/mL concentrate for solution for infusion, 1,800mg solution for subcutaneous injection (Darzalex®) is routinely available in line with national guidance (SMC 2536).
Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).
In a phase III study, daratumumab, in combination with lenalidomide and dexamethasone, improved progression-free survival compared with lenalidomide plus dexamethasone in patients with newly diagnosed multiple myeloma ineligible for ASCT.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Daratumumab subcutaneous formulation is not intended for intravenous administration and should be given by subcutaneous injection only, using the doses specified.
Daratumumab should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available.

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It is important to check the vial labels to ensure that the appropriate formulation (intravenous or subcutaneous formulation) and dose is being given to the patient as prescribed.
For patients currently receiving daratumumab intravenous formulation, daratumumab solution for subcutaneous injection may be used as an alternative to the intravenous daratumumab formulation starting at the next scheduled dose.
Pre- and post-injection medicinal products should be administered to reduce the risk of infusion-related reactions (IRRs) with daratumumab. **FTEAM**

8.5. NCMAG 109 - PEMETREXED (OFF-LABEL USE, NSCLC)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for the off-label use of pemetrexed [in combination with cisplatin] as adjuvant treatment for patients with completely resected stage IIA to IIIA non-squamous, non-small-cell lung cancer (NSCLC).

The Group noted that:
- pemetrexed is licensed and included on formulary for other indications
- during COVID-19, pemetrexed in combination with cisplatin was recommended for use by the National Cancer Medicines Advisory Group (NCMAG) for fully resected stages IB (poor risk features only) to IIIA non-squamous NSCLC in patients suitable for adjuvant chemotherapy, who would otherwise receive adjuvant treatment with the combination of vinorelbine and cisplatin
- the standard of care [for this indication] is vinorelbine plus cisplatin
- evidence comes from JIPANG and TREAT which concluded similar efficacy between pemetrexed plus cisplatin and vinorelbine plus cisplatin
- in JIPANG, the median recurrence-free survival was 37.5 months for vinorelbine and 43.4 months for pemetrexed
- in TREAT the clinical feasibility rate was 75% and 95% for vinorelbine plus cisplatin and pemetrexed plus cisplatin respectively
- JIPANG also showed that pemetrexed plus cisplatin is associated with fewer side effects, less hospital visits and a higher completion rate than the vinorelbine regimen
- the cost mininisation analysis completed by NCMAG concluded that when national framework prices were used, the pemetrexed regimen was estimated to produce per patient cost savings versus intravenous and oral vinorelbine

The Group accepted the restricted local need for the off-label use of pemetrexed infusion, in combination with cisplatin, as adjuvant treatment for patients with completely resected stage IIA to IIIA non-squamous, NSCLC, in line with NCMAG 109.

NCMAG 109 - Pemetrexed infusion is routinely available in line with national guidance (NCMAG 109).
Indication under review: [off-label use] in combination with cisplatin as adjuvant treatment for patients with completely resected stage IIA to IIIA non-squamous, non-small-cell lung cancer (NSCLC).
This advice applies only in the context of the NHS Scotland national framework contract, delivering the cost-effectiveness results upon which the decision was based, or a national framework contract or list price that is equivalent or lower.
The generic product available at the lowest acquisition cost should be prescribed.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Pemetrexed must only be administered under the supervision of a physician qualified in the use of anti-cancer chemotherapy. **FTEAM**

8.6. SBAR - NALOXONE 1.26MG NASAL SPRAY

There were no declarations of interest recorded in relation to this product.

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The Group considered the request for a new strength of naloxone 1.26mg nasal spray as emergency therapy for known or suspected opioid overdose.

The Group noted that:

- Prenoxad® 1mg/mL solution for injection in a pre-filled syringe and Nyxoid® 1.8mg nasal spray are already included on formulary
- the new generic nasal spray contains a lower dose of naloxone per single spray (1.26mg/spray) when compared with Nyxoid® (1.8mg/spray), but the administration device and route of administration are identical
- with respect to reversing the symptoms of opioid overdose, 1.26mg intranasal naloxone is considered equally effective compared with the 0.8mg via the intramuscular route
- the 'pebble' contains two devices per pack, so a second dose is available if required
- Nyxoid® is licensed from 14 years but Prenoxad® and generic naloxone nasal spray are licensed for use in adults only
- the three preparations are requested on formulary to provide patient choice, with a potential to increase the number of people carrying the product
- the naloxone 1.26mg nasal spray:
  - is packaged in an ergonomic and robust 'pebble' casing that protects the two nasal sprays from damage, is ready to use in an emergency (does not require any assembly before administration)
  - the portability of the 'pebble' may encourage people to carry it, whilst ensuring two nasal sprays are carried together if a second dose is needed
  - has a band stretched around the pebble casing reminding the carrier to call for emergency medical services before administering the first dose

The Group accepted the restricted local need for naloxone 1.26mg nasal spray as an additional product for emergency therapy for known or suspected opioid overdose.

SBAR - Naloxone 1.26mg nasal spray is routinely available in line with local guidance.
Indication under review: for immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings.
Naloxone 1.26 mg nasal spray is intended for immediate administration.
Naloxone 1.26mg nasal spray is indicated in adults.
Naloxone 1.26mg nasal spray is not a substitute for emergency medical care.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. — **FTEAM**

8.7. SBAR - TESTOSTERONE GEL (OFF-LABEL REQUEST FOR USE IN WOMEN)

There were no declarations of interest recorded in relation to these products.

The Group considered the request for the off-label use of testosterone gel for menopausal women with low libido, where HRT has been optimised and significant contributing factors have been excluded.

The Group noted that:

- this is a request for the off-label use of an existing formulary preparation
- off-label use of testosterone gel is supported nationally and internationally
- in the UK, use is supported by the British Menopause Society (BMS) and NICE guideline 23 - Menopause: diagnosis and management.
- there is a product licensed in Australia but in the UK MAHs are unlikely to progress license extensions for this indication in the near future
- the BMS recommends a female physiological dose of 5mg per day
- high doses of testosterone in women can lead to potentially irreversible side effects

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- the BMS Tool for clinicians provides suggested dosing for three products:
  - *Testim® gel 1% testosterone gel in 5mL tubes: starting dose 0.5mL (5mg) per day making each tube last for 10 days (however this company is exiting the UK market)*
  - *Tostran® (2% testosterone gel in a canister containing 60g): starting dose 1 metered pump of 0.5g = 10mg on alternate days – each canister should last 240 days*
  - *Testogel® (2.5g sachets containing 40.5mg testosterone): starting dose 1/8 of a sachet/day = approx. 5mg/day i.e. each sachet should last 8 days*
- the Menopause consultant specialists confirm that:
  - prescribing should be undertaken only when prerequisites are met (patient has reached the menopause, management is for low libido only, hormone replacement therapy (HRT) dose has been optimised and sufficient time lapsed to assess benefits, biopsychosocial issues addressed)
  - monitoring is required at 6-12 weeks and then review at 6 months. If no benefit after 6 months, treatment should be discontinued.
- Clinical evidence – there is some evidence for use for low libido, and use is supported by national guidance
- Cost-effectiveness - no cost/QALY data, but individual patient cost is low to moderate
- Health gain - improved quality of life is expected for those benefiting from treatment, and there is a stopping rule for those not benefitting
- Service impact – there is the potential for a positive patient and service impact. Inclusion of testosterone [off-label] on the formulary, supported by guidance for Primary Care to ensure that only appropriate patients are referred to the specialist menopause service, has the potential to improve the patient experience and reduce the number of inappropriate referrals.
  This request has the potential to contribute to the Scottish Government Women's Health Plan: A plan for 2021-2024.
- Equity – formulary inclusion will bring NHS Grampian in line with neighbouring Health Boards, and use is routinely available in NHS England and NHS Wales (in line with NICE CG23).
- Safety - There is a lack of long-term data, including safety data, for the off-label use of testosterone in women. However, more data may become available as in Australia AndroFeme® 1 (cream containing 1% w/v (10mg/mL) testosterone) is licensed for the treatment of hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.

The Group accepted the restricted local need for the off-label use of topical testosterone gel for menopausal women, with low libido, where HRT has been optimised and significant contributing factors have been excluded. Acceptance is subject to provision of prescribing and referral guidance for Primary Care to ensure that appropriate monitoring is undertaken, only appropriate patients receive a trial of treatment and are referred to the specialist menopause service.
When the guidance is published treatment can be reclassified to allow prescribing in Primary Care.

Until the prescribing and referral guidance is published prescribing should remain within the managed service.

SBAR - Testosterone gel is routinely available in line with local guidance.
Indication under review: [off-label use] in menopausal women, with low libido, where HRT has been optimised and significant contributing factors have been excluded.
It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. **FTEAM**

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9. SMC PROVISIONAL ADVICE ISSUED – SEPTEMBER 2023

The Group noted the SMC provisional advice issued September 2023.

If the negative SMC recommendation is published next month, this medicine will not be included on the formulary for the indication in question.

10. SMC PUBLISHED ADVICE - SEPTEMBER 2023

The Group noted the SMC advice published September 2023.

Following publication of the negative SMC recommendation, for mosunetuzumab (Lunsumio)▼ SMC 2542, and the non-submission statements, for nivolumab (Opdivo) SMC 2620 and crizotinib (Xalkori) SMC 2621, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2543 ibrutinib (Imbruvica®) (submission received)
- SMC 2596 vutrisiran (Amvuttra®)▼
- SMC 2603 rimegepant (Vydura®)▼ (submission expected)

Local advice for these medicines and indications will be included in the September 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2583 - ELADOCAGENE EXUPARVOVEC 2.8 × 10^{11} VECTOR GENOMES (VG)/0.5ML SOLUTION FOR INFUSION (UPSTAZA®) AND SMC 2560 - OLIPUDASE ALFA 20MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION (XENPOZYME®)

There were no declarations of interest recorded in relation to these products.

In line with local processes, and pending confirmation that these medicines are available for prescribing within the ultra-orphan pathway, the Formulary Group recorded both medicines as 'not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).'

SMC 2583 - Eladocagene exuparvovec 2.8 × 10^{11} vector genomes (vg)/0.5mL solution for infusion (Upstaza®)▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of patients aged 18 months and older with a clinical, molecular, and genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency with a severe phenotype.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

SMC 2560 - Olipudase alfa 20mg powder for concentrate for solution for infusion (Xenpozyme®)▼ is not routinely available in NHS Grampian.
Indication under review: as an enzyme replacement therapy for the treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients with type A/B or type B.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

ITEM	SUBJECT	ACTION

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - SEPTEMBER 2023

The Chair reported that the National Institute for Health and Care Excellence (NICE) has commenced a multiple technology appraisal (MTA) of ivacaftor-tezacaftor, elexacaftor, tezacaftor-ivacaftor and lumacaftor-ivacaftor for treating cystic fibrosis [ID3834]. Given similar circumstances regarding access arrangements and data collection to date, NICE and SMC have agreed to collaborate on the MTA, which will ensure alignment of guidance on these therapies across England and Scotland. Further information can be found in a joint statement, which is available on the SMC website https://www.scottishmedicines.org.uk/about-us/latest-update/joint-statement-nice-and-smchis-collaboration-on-mta-for-cystic-fibrosis/.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update August 2023), 12.3 (MedWatch Vol.4 Issue 3 September 2023), and 12.3 (Grampian Antimicrobial Management Team (AMT) minute May 2023) were noted.

13. AOCB

PHARMACY FIRST APPROVED LIST

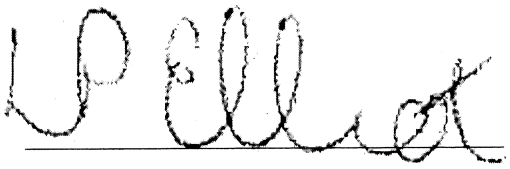
Ms Doney confirmed that review of the Pharmacy First Approved List is complete and most of the recommendations discussed previously were accepted.
The steering Group rejected removal of Simple Linctus at this time, with a plan to review the evidence to support use and usage figures a future date.

SURVEY

Mrs Standen confirmed that in the next few weeks a survey would be sent to members requesting feedback on the content, layout, and presentation of the reviews. **CS**

DATE OF NEXT MEETING

Tuesday 17 October 2023 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 17 OCTOBER 2023**